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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,056	08/03/2000	Clifford A. Lingwood	STI-201CN2	1948

959 7590 09/30/2002

LAHIVE & COCKFIELD  
28 STATE STREET  
BOSTON, MA 02109

EXAMINER
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BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/30/2002

*A*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/632,056

Applicant(s)

LINGWOOD ET AL.

Examiner

Gabriele E. BUGAISKY

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/386957.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 1653

## **DETAILED ACTION**

### ***Oath/Declaration***

It is noted that one of the inventors (Farkas-Himsley) is listed on the face of patent numbers 5968894 and 6228370, as deceased. Any papers updating the status of the inventors, which were filed in related cases, are not automatically incorporated in other applications. Applicants are requested to update the information on the original declaration.

### ***Information Disclosure Statement***

The listing of references in the specification ( page 3, line 33 to page 6, line 11) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by Applicants on PTO-1449 or by the examiner on form PTO-892, they have not been considered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-12 and 14-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cancer cells that are Gb<sub>3</sub> positive, does not reasonably provide enablement for the killing of any cancer cell . The specification does not enable any

Art Unit: 1653

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification clearly teaches that verotoxin attaches to the globo series glycolipid globotriaosylceramide and requires terminal gal  $\alpha$ -1-4 gal residue for binding (page 1, lines 30-32 and shows in numerous Examples that cancer cells expressing Gb<sub>3</sub> are sensitive to verotoxin. The specification does not teach any killing of cancer cells that are not Gb<sub>3</sub> positive; thus, the presence of the verotoxin binding site is a necessary requisite for its role in cell death. While it is not unreasonable to test whether a specific cancer cell expresses Gb<sub>3</sub>, and then treat the cell with verotoxin, in the absence of any further guidance, it is deemed undue experimentation to determine whether any randomly chosen cancer cell is susceptible to verotoxin.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mangeny *et al.* (reference B7 of paper #3). The reference teaches the apoptosis (killing) of cancer cells following administration of verotoxin. It is deemed anticipatory for the claimed subject matter of claims 1-14 and 18 because the reference supplies Burkitt's lymphoma cells that have been originally obtained from a human patient, killed *in vitro*, are Gb<sub>3</sub> positive and because Burkitt's lymphoma is a tumor.

Art Unit: 1653

Claims 1-18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mangeney *et al.* The teachings of the reference are discussed above; the reference, however, is silent on the type of verotoxin applied to the cells. One of the holotoxins was used and it would have been obvious for one of ordinary skill in the art at the time of the invention to substitute any of the known variants.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6228370. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent recite treatment of neoplasia in mammals, whereas the instant claims recite killing cancer cells from a patient. Killing cancer cells treats neoplasia.

Claims 11-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 5968894. Although

Art Unit: 1653

the s conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to specific types of neoplasia, whereas the instant claims extend to any cancerous cell. . Killing cancer cells treats neoplasia.

Claims 11-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-14 of copending Application No. 09/877399 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method of killing cancer cells with verotoxin whereas the opening application recites a method of treating drug resistant tumors with verotoxin. Killing the drug resistant cancer cells treats the drug resistant tumor..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15-12:15 M, 8:15-1:15 Tu-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for

Art Unit: 1653

the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

  
**GABRIELLE BUGAISKY**  
**PRIMARY EXAMINER**

Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

September 30, 2002